



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

NAFTA Technical Working Group on Pesticides Dec. 14-16, 2005, Charleston, South Carolina

Meeting Summary

The North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (TWG) met in Charleston, South Carolina from December 14-16, 2005. Representatives of the U.S., Mexican, and Canadian governments as well as stakeholders from all three NAFTA countries participated in the meeting.

Jim Jones, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency (EPA), welcomed all participants and chaired the U.S.-hosted meeting. He outlined three EPA activities of interest to the NAFTA Technical Working Group: the Registration Review Process, U.S. Data Requirements (Code of Federal Regulations, Part 158; Data Requirements for Registration, or CFR 158), and a new Human Studies rule. Mr. Jones then invited his Canadian and Mexican counterparts on the NAFTA Technical Working Group Executive Board to provide their country reports.

Dr. Karen Dodds, Executive Director, Pest Management Regulatory Agency (PMRA), Health Canada, underscored the two key priorities of the PMRA - improvements both in communications and stakeholder involvement. She indicated that the new *Pest Control Products Act* (yet to come into force) encourages increased transparency in several areas. Dr. Dodds outlined two critical issues in the context of the NAFTA Technical Working Group: Canada's revocation of the 0.1ppm Maximum Residue Limit and the Own Use Import task force.

Amada Velez, General Director of Food Safety, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria¹ / Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación² (SENASICA/SAGARPA), Mexico, indicated that the new Mexican Pesticide Regulation came into force on March 29, 2005. She outlined the new registration process that Comisión Federal para la Protección contra los Riesgos Sanitarios³ (COFEPRIS) now oversees with the assistance of technical opinions from the two agencies, Secretaría de Medio Ambiente y Recursos Naturales⁴ (SEMARNAT) and SAGARPA. Mrs. Velez explained that Mexico's involvement in the NAFTA Technical Working Group would currently be limited to the following areas: Trade Irritant Resolution, NAFTA Residue Zone Maps, United States Department of

¹ National Service for Sanitary Food Safety and Quality

² Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food

³ Federal Commission for Prevention of Sanitary Risks

⁴ Secretary of Environment and Natural Resources

Agriculture's Interregional Research Project Number 4 (IR-4)/Minor Use, Worksharing on Registration, and Risk Reduction through Worker Safety Programs.

The Secretariat provided a report on recent consultations with stakeholders held to obtain public input towards the development of the Charleston meeting agenda.

The Co-Chairs for the Regulatory Capacity Building Subcommittee and Risk Reduction Subcommittee presented the results from their refreshment exercises. The goal of the refreshment exercises was to take stock of subcommittee efforts to date and propose directions for future work. The Executive Board accepted the recommendations of both subcommittees, including the close out and streamlining of various projects and approval of new projects.

Recommendations from the three breakout group discussions are reflected in this summary, as appropriate. Each breakout group reported out in plenary on their deliberations; the presentations from each session are attached separately (Attachment 1). A list of recommendations from each breakout group and the Executive Board response is also provided (Attachment 2). The topics covered the breakout groups are as follows: Maximum Residue Limit Harmonization/Joint Reviews; non-agricultural pesticides issues; and NAFTA Labels.

The Executive Board was provided with country updates on the regulatory status of lindane and committed to continue active exchange of new information.

The Executive Board discussed the harmonization of data requirements and agreed to develop a Technical Working Group project sheet addressing data requirements for conventional chemicals, biopesticides, and anti-microbials which are the subject of proposed U.S. rule-making under 40 CFR Part 158, 158 L&M, and 158 W, respectively. The project sheet will take into consideration recommendations from the breakout group on non-agricultural pesticides issues to focus on: 1) a tiered approach to review of non-food residential use pesticides, and 2) antimicrobial data regarding efficacy requirements and associated claims.

The Executive Board noted the significant accomplishments of the joint review program, in that 2005 has been the most active year thus far for registrations of new conventional chemicals. Notable achievements include: the acceptance of four new active ingredients and 22 registered new uses; the establishment of three workshare programs; and the completion of one minor use pilot project. Due to the success of the NAFTA joint review program, the NAFTA countries are actively pursuing worksharing opportunities with Organisation for Economic Co-operation and Development (OECD) countries and other international partners.

Stakeholders highlighted concern that differences in product registration between NAFTA countries continue to cause trade issues related to maximum residue limits/ tolerances for traded commodities and access to pest control products. The Executive Board acknowledged that resolving these issues continues to be a high priority, and agreed to establish a government task force to develop more effective options to further improve coordinated decision-making. These

would build on current efforts towards the goal of harmonizing Maximum Residue Limit and registration decisions.

The Executive Board agreed to make the standard operating procedures for conventional chemical and minor use joint reviews operational and approved them for public release. Interested stakeholders are welcome to provide feedback or raise questions, as appropriate. Although the Mexican Registration Regulation does not allow a joint review process as outlined in the standard operating procedures, Mexico will continue to participate in joint review activities, as appropriate.

The NAFTA Industry Working Group presented to the Executive Board and Stakeholders a proposed process to address equal access for minor use crops and incentives for industry to participate in the joint review process. The Technical Working Group welcomed the Industry Working Group proposal and looks forward to working with registrants to further refine suggested approaches. The Technical Working Group is open to joint review/workshare proposals on specific new substances made to countries jointly. Mexico is interested in participating as an observer. The Executive Board accepted the recommendation, from the breakout group on maximum residue limits / tolerances, for an industry analysis of reasons joint review options were not pursued when registering new substances.

The Executive Board discussed issues related to minor use, including information on minor use field trials and an update on international crop groupings. The Executive Board approved a new project to ensure a coordinated approach to crop grouping and requested representatives from IR-4, Agriculture and Agri-Food Canada (AAFC), EPA and PMRA to draft a project sheet under the Food Residue Subcommittee that outlines mutual planning and development for establishing crop groupings. While the current Mexican legislative framework does not allow for crop grouping, SAGARPA will also participate to assist in possible future crop grouping implementation. It was also agreed that IR-4 and/or AAFC would submit crop grouping proposals simultaneously to both EPA and PMRA. With regard to international efforts, EPA and PMRA agreed to participate in the Codex Committee on Pesticide Residues crop grouping project to promote consistent, coordinated global approaches.

The Executive Board discussed the implementation and impact of NAFTA labels for non-agricultural products. A draft label guidance document was successfully used by several registrants to create mock NAFTA labels accepted and approved by both the EPA and Health Canada's Therapeutic Products Directorate, but with different label claims for each country. The EPA and Therapeutic Products Directorate will continue to discuss harmonization of label claims, which would allow a single label to be used in both countries.

The Executive Board agreed to consider recommendations from breakout group discussing non-agricultural pesticides issues to allow for public comment on a revised label guidance document, to resolve country differences with label claims, to develop a mechanism to address further changes, and to consider future pilot projects, including: rodenticides, repellents, and ornamentals. The next pilot non-agricultural NAFTA label to be pursued will be for a non-agricultural pesticide already regulated by PMRA and EPA.

Noting the importance of NAFTA labels, the Technical Working Group agreed to facilitate a stakeholder process to explore options for developing and implementing NAFTA labels. Specifically, a Task Force consisting of industry, growers, and government representatives will be established in the near future to consider recommendations from the breakout group on NAFTA labels.

Implementation and Impact of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), were also discussed by the Executive Board and stakeholders. The breakout group on non-agricultural pesticides issues expressed support for many aspects of GHS implementation. The PMRA and EPA continue their commitment to GHS and agreed that implementation could occur in a staged manner among sectors. The Executive Board agreed that further work is needed to provide GHS information to stakeholders and that EPA and PMRA will remain in continuous contact regarding sector status.

The Executive Board received an update on domestic efforts related to inerts/formulants and agreed that country leads would meet shortly to share information and identify areas for possible worksharing.

The Food Residue Subcommittee reported on progress towards resolving priority trade irritants for the Pulse and Tomato pilot projects, and presented a new project on potatoes, which was approved by the Executive Board. The Executive Board accepted a recommendation from the breakout group on maximum residue limits/joint review to conduct a case study on tomatoes for harmonized NAFTA maximum residue limits, under disparate use patterns and conditions, to be undertaken by Commodity-based project leads with participation by industry.

The Executive Board endorsed next steps for finalizing and institutionalizing the Maximum Residue Limit / Tolerance Statistical Methodology/Calculator and requested that plans for adoption and implementation be reflected in the project sheet.

Canada provided an update on the development and implementation of the General 0.1ppm General Maximum Residue Limit revocation policy. The analysis of the policy issues has been completed and the next consultation document is planned for release by spring 2006. Leads will provide a progress report on exploring approaches to the establishment of Canadian tolerance for maximum residue limits that have a corresponding U.S. tolerance greater than 0.1ppm.

Leads for the Residue Trial Efficiencies Project agreed to develop a workplan outlining timeframes and next steps for the development of a guidance document and full implementation. The project sheet will be revised and combined with the project sheet on updating agricultural production figures. Until the guidance is available, the Executive Board agreed that for now registrants seeking the 25% reduction in required residue trial should approach the EPA and PMRA jointly. If the agencies cannot accept specific proposal, then they will clearly communicate the rationale to registrants.

The Executive Board supported approaches presented by the EPA and PMRA to facilitate collection and analysis of field trial residue data from Zones 5, 5A, and Zones 1 and 1A to support minor use label expansion. Project leads will develop an explanation of the proposals for public release in early 2006.

The Executive Board discussed the possible development of a global analytical framework for residue trials. The United States agreed to undertake some analysis of existing residue chemistry data representing a range of growing and use conditions to determine if a global framework could be established. The results of this analysis will be reported and discussed at the next Executive Board meeting. Additionally, the breakout group on maximum residue limits/joint review expressed support for a global specialty crop initiative proposed by IR-4.

The Food Residue Subcommittee presented the NAFTA Import Tolerance Document to the Executive Board, and plans for coordinating public release. The Executive Board approved the document and the next steps for publication.

The Executive Board received an update on EPA/PMRA joint planning/coordination efforts around scheduling and implementation for re-registration/re-evaluation. Program leads outlined proposed next steps and timelines. A detailed plan for worksharing will be presented at the NAFTA Technical Working Group Executive Board meeting in November/December 2006. The breakout group on maximum residue limits/joint review endorsed up-front coordination on the U.S. registration review and Canadian re-evaluation programs as a mechanism for identification and possible resolution of trade irritants.

The Executive Board discussed the outcomes of EPA/PMRA information exchange activities related to domestic performance indicators and implications for developing Technical Working Group indicators. The EPA and PMRA will meet to explore harmonization of performance indicators for domestic programs. Mexican authorities will participate, as appropriate, as it relates to Technical Working Group projects in which Mexico is participating.

Each of the breakout groups was also tasked with proposing performance indicators that could serve as measures of success for the issues discussed. These are included in the attached presentations. Relevant Subcommittee chairs will consider the recommendations to develop performance indicators for each Subcommittee.

The Executive Board was presented with information on Mexico's program to reduce direct and indirect exposure to pesticides in migrant agricultural workers and their families, and to promote proper disposal of empty pesticide containers. The goals of the program are to standardize criteria, to harmonize trilateral actions of risk communication, to augment training and occupational hygiene and safety, to share information and experience with pesticides among migrant agricultural workers and to gather scientific evidence that trilateral intervention has a positive impact on public health.

The Executive Board expressed support for further exploration of Mexico's proposal on worker safety and committed to following up through appropriate trilateral communications.

The Technical Working Group discussed the issue raised by breakout group on non-agricultural pesticides issues, regarding access to confidential business information in the Canadian Reading Room. Despite slight differences in domestic approaches, the United States and Canada concluded that the countries are sufficiently consistent in their treatment of confidential business information making a legal interpretation unnecessary. Nonetheless, the Technical Working Group agreed to disseminate additional information to stakeholders by developing and issuing a revised fact sheet on this topic.

Mexican and Canadian members of the NAFTA Industry Technical Working Group on Pesticides provided the Executive Board with an overview of their stewardship programs, highlighting the success of the pesticide container collection programs in their respective countries.

The next Executive Board meeting will take place in May/June 2006 in Mexico. The subsequent government-stakeholder meeting will be scheduled for November/December 2006 in Canada.

Attachment 1

Break Out Group (BOG) presentations made to plenary session of the
Meeting of the NAFTA Technical Working Group on Pesticides

Dec. 14-16, 2005, Charleston, SC

Directions as provided to each BOG are inserted before each presentation

BOG 1: MRL Harmonization (Retrospective/Prospective Approaches)

The focus of this BOG discussion is to exchange views on lessons learned from the commodity-based projects (Pulse/Tomato crops) in resolving trade irritants, practical approaches (in particular, prospective approaches) to increasing the rate of MRL harmonization among the NAFTA countries, ways of encouraging more Joint Review submissions for conventionals and biopesticides, including a more detailed review of the new Joint Review Standard Operating Procedures that incorporate various improvements to the Joint Review process. The BOG will give a report out in plenary to the NAFTA TWG, outlining recommendations for addressing key issues and proposed performance indicators that could serve as measures of success in MRL harmonization and minimization/resolution of trade irritants.

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Topics Discussed

- Joint review submissions
- Harmonized MRLs
- IR-4 Global Initiative
- Registration Review and Re-evaluation
- Performance objectives

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Joint Review Submissions

- One size does not fit all
 - Market analysis
 - Geographic restrictions
- Valuable to growers, regulators, and registrants
- Communication is Key
- Harmonized data requirements need to be addressed
- Case study maybe helpful to understand
- Communicate about joint review availability for new uses on already registered products

3

Harmonized MRLs

- One NAFTA MRL
- Disparate Use Pattern
 - Legitimate geographic differences
 - Grower use- tolerances, labels, accountability
- Import Tolerances
 - Risk cup issues
- Case Study, such as tomatoes

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IR-4 Global Initiative

- Obtaining MRLs in countries outside of the US
- Collection of data and provide to other countries
- Formatting and actual submissions
- CODEX, EU, JMPR
- Housed under current IR-4 program

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Registration Review and Re-evaluation

- Better coordination up front
- Better communication
- Address legal framework
- Vehicle to address trade irritants

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Performance objectives

- Number of joint review submissions and decisions
- Number of NAFTA MRLs set
- Number grower identified trade irritants reduced
- Number of trade irritant problems resolved
- Number of new products registered concurrently in NAFTA countries
- Number of registrations that “beat” timelines
- Increase the distribution of information and add training to help growers get information from the NAFTA TWG
- Increase number of RR compounds concurrently registered

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BOG 2: Non-Agricultural Issues

The focus of this BOG discussion is to exchange views on priority issues specific to non-agricultural pesticides, including harmonization of non-agricultural data requirements, implementation of the Globally Harmonized System of Hazard Classification and Labelling (GHS), and confidential business information (CBI) issues related to the Canadian PCPA. The BOG will give a report out in plenary to the NAFTA TWG, outlining recommendations for addressing key issues and proposed performance indicators that could serve as measures of success in this area, that will be reported out in plenary.

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- Harmonization of Non-Agriculture Requirements
- GHS Implementation
- CBI in the Canadian Reading Room
- NAFTA Label
- Performance Indicators

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Harmonization of Non-Ag Data Requirements

- Existing vs proposed requirements
- Conventional and Antimicrobial Pesticides
 - 40 CFR 158
 - 40 CFR 158 new subpart W
- Key areas of focus
 - 1. Non-food residential use pesticides- Tiered approach
 - 2. Antimicrobial data- efficacy requirement and associated claims

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GHS Implementation

- Support for:
 - 1. total harmonization in NAFTA
 - 2. Phase in implementation, i.e. long transition times
 - 3. Coordinated implementation
 - 4. Stakeholder process in US
 - 5. More info on benefits of GHS
 - 6. Lead agency in US
 - 7. Harmonization between sectors within countries
 - 8. Possible utility of North American meeting with all agencies and sectors should be explored by government and industry alike.

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CBI in Reading Room

- Raise question about making information available in reading room constitute public disclosure.
- Request written legal interpretation of above be made publicly available.

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NAFTA Label

- Public comment on revised label guidance document
- Resolve differences in claims allowed
- Mechanism for further change
- Future pilot projects
 - Consumer, rodenticides, repellents, ornamentals
 - Joint review/ NAFTA label for category B (new end use product) submission

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Performance Indicators

- Deliverables with action steps
- Timetables/ timelines
- Reduction in differences/ trade irritants
- Show progress in action items

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BOG 3: NAFTA Labels

The focus of this BOG discussion is to exchange views on challenges and opportunities associated with the development and use of NAFTA labels. The BOG will give a report out in plenary to the NAFTA TWG, outlining recommendations for addressing key issues and proposed performance indicators that could serve as measures of success in this area.

NAFTA Label

- Label that meets regulatory requirements of more than one NAFTA country. With the intent that these products can easily cross borders. Sharing of common language as much as possible.

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Discussion

- WHY a NAFTA label?
 - Creating a North American market for pesticides
 - Price
 - Supplies
 - Facilitate Trade
- Focused on NAFTA labels & Alternatives

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Options

- NAFTA label
- OUI (Own Use Import)
- Index List
- State/Province Specific to NAFTA country label eg., 24 (c)

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Proposals

1. Product Index/Cross Reference
 - Pilot Proposal (create task force = government & stakeholders)
 - Identify list of products for consideration
 - Product profile
 - Reduced Risk
 - Registered under JR
 - Established Chemical Identity
 - Similar Use Pattern
 - Candidate Products to be designated as importable

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Proposals

2. NAFTA Label

- Task Force (Government/Registrant/Stakeholder) created; identifies a product registered US/CA and considers the following:
 - Issues
 - Legal (Change in the law)
 - Regulatory (Change in Regulation)
 - Process
 - State/Province input
 - Specific National Initiatives
 - Label Format
 - Compliance
 - Use pattern/Usage
 - Endangered Species
 - Adoption of the Label
- Incentives to Registrants

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Attachment 2
Stakeholder Recommendations and Executive Board Responses

| Stakeholder Recommendations | Executive Board Responses |
|--|---|
| <p><u>Maximum Residue Limits</u> Breakout group on maximum residue limit harmonization/joint reviews recommended analysis of reasons why Joint Review options were not pursued</p> | <p>The Executive Board accepted the recommendation for an industry analysis of reasons joint review options were not pursued when registering new substances.</p> |
| <p><u>Maximum Residue Limits</u> Breakout group on maximum residue limit harmonization/joint reviews recommended a case study to investigate issues of disparate use patterns, geographic differences, grower use-tolerances, labels, and accountability</p> | <p>The Executive Board accepted a recommendation to conduct a case study on tomatoes for harmonized NAFTA maximum residue limits, under disparate use patterns and conditions, to be undertaken by Commodity-based project leads with participation by industry.</p> |
| <p><u>Interregional Research Project #4 (IR-4) Global Initiative</u> Breakout group on maximum residue limits/joint review expressed support for a global specialty crop initiative proposed by IR-4.</p> | <p>Executive Board expressed appreciation for stakeholder endorsement</p> |
| <p><u>Performance Objectives</u> Several recommendations for performance measures provided by breakout groups</p> | <p>Relevant Subcommittee chairs will consider the recommendations to develop performance indicators for each Subcommittee. Mexican authorities will participate, as appropriate, as it relates to Technical Working Group projects in which Mexico is participating</p> |
| <p><u>Trade Issues</u> Stakeholders highlighted concern that differences in product registration between NAFTA countries continue to cause trade issues related to maximum residue limits/ tolerances for traded commodities and access to pest control products.</p> | <p>The Executive Board acknowledged that resolving these issues continues to be a high priority, and agreed to establish a government task force to develop more effective options to further improve coordinated decision-making.</p> |

| Stakeholder Recommendations | Executive Board Responses |
|--|--|
| <p><u>Confidential Business Information / Reading Room</u></p> <p>Breakout group on non-agricultural pesticides issues requested a legal interpretation from governments regarding the availability of information in reading room constituting public disclosure</p> | <p>The Technical Working Group agreed to disseminate additional information to stakeholders by developing and issuing a revised fact sheet on this topic</p> |
| <p><u>Joint Review Process</u></p> <p>Industry Working Group provided a presentation on Same Time Equal Access to Products, and recommended improved coordination to facilitate better timing of decision making.</p> | <p>The Technical Working Group is open to joint review/workshare proposals on specific new substances made to countries jointly. Mexico is interested in participating as an observer.</p> |
| <p><u>Harmonization of Non-Agricultural Data Requirements</u></p> <p>Recommendation from the breakout group on non-agricultural pesticides issues that harmonization efforts focus on a tiered approach for non-food residential use pesticides, and on antimicrobial data pertaining to efficacy requirement and associated claims</p> | <p>Executive Board agreed to develop a Technical Working Group project sheet addressing data requirements for conventional chemicals, biopesticides, and anti-microbials which are the subject of proposed U.S. rule-making under the Code of Federal Regulations (40 CFR) Part 158, 158 L&M, and 158 W, respectively.</p> |
| <p><u>Globally Harmonized System for Labelling</u></p> <p>Breakout group on non-agricultural pesticides issues expressed support for several aspects of Globally Harmonized System implementation.</p> | <p>The PMRA and EPA continue their commitment to GHS and agreed that implementation could occur in a staged manner among sectors. The Executive Board agreed that further work is needed to provide GHS information to stakeholders and that EPA and PMRA will remain in continuous contact regarding sector status.</p> |
| <p><u>NAFTA Label - Agricultural</u></p> <p>Breakout group on NAFTA labels suggested further investigation of the NAFTA label, and a potential product index to address issues behind need for NAFTA label.</p> | <p>Noting the importance of NAFTA labels, the Technical Working Group agreed to facilitate a stakeholder process to explore options for developing and implementing NAFTA labels. Specifically, a Task Force consisting of industry, growers, and government representatives will be established in the near future to consider recommendations from the breakout group on NAFTA labels.</p> |

| Stakeholder Recommendations | Executive Board Responses |
|--|---|
| <p><u>NAFTA Label – Non-Agricultural</u></p> <p>Breakout group on non-agricultural pesticides issues recommended that: public be allowed comment on revised label guidance document; that efforts be made to resolve difference in claims allowed; mechanisms be considered for further changes; and that pilot projects be considered.</p> | <p>Executive Board agreed to consider these recommendations and to forward them to program leads to be addressed.</p> <p>The next pilot non-agricultural NAFTA label to be pursued will be for a non-agricultural pesticide already regulated by PMRA and EPA</p> |